

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference M/40226-PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP00/07807	International filing date (day/month/year) 10 August 2000 (10.08.00)	Priority date (day/month/year) 11 August 1999 (11.08.99)
International Patent Classification (IPC) or national classification and IPC C12N 15/53, 15/82, 9/02, 1/21, A01H 5/00, C07D 311/72, C12P 17/06		
Applicant SUNGENE GMBH & CO. KGAA		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input checked="" type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 09 March 2001 (09.03.01)	Date of completion of this report 02 January 2002 (02.01.2002)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed
- ☒ the description:
pages 1-21, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the claims:
pages 1-18, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the drawings:
pages 1/5-575, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the sequence listing part of the description:
pages 22-29, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	2, 6, 9	YES
	Claims	1, 3-5, 7, 8, 10-18	NO
Inventive step (IS)	Claims		YES
	Claims	1-18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims		NO

2. Citations and explanations

1. The subject matter of the first claim contains 3 alternative subjects:
 - a) expression cassette containing a nucleic acid sequence that codes for HPPD or a functional equivalent thereof;
 - b) expression cassette containing a nucleic acid sequence that is capable of inhibiting HGD;
 - c) expression cassette containing a) and b).

Novelty (PCT Article 33(2))

2. WO-A-99/04021 (D1) describes a nucleic acid that codes for an HPPD from barley, and tobacco plants that are transformed using a corresponding expression cassette (Example 7, page 27). The tobacco plants transformed with the constructs have a higher tocopherol concentration in comparison with non-transformed plants.

This part of the subject matter (see a) above) of Claims 1, 3 (see D1, page 1, second paragraph), 4, 5 ("functional equivalent"), 7-8 and 10-18 is therefore anticipated by D1 in a manner prejudicial to novelty.

3. Claims 2, 6 and 9, which are dependent on this part, are novel.
4. The subjects of Claim 1 designated b) and c) above and the claims dependent thereon are considered novel.

Inventive step of alternatives b) and c) (PCT

Article 33(3))

5. D1 is the closest prior art, the teaching of which is specified above. In comparison thereto, the present application proposes, in order to increase the tocopherol content of plants, to transform said plants using a construct that codes for a nucleic acid that is capable of inhibiting HGD activity, or using a construct(s) that codes for HPPD and a nucleic acid and is capable of inhibiting HGD activity.

The application therefore addresses the problem of preparing plants with an increased tocopherol content.

The application does not show whether the proposed alternatives can actually solve the problem (see Example 4). Consequently, an inventive step cannot be acknowledged for the above problem.

If it were possible to submit comparative results that show an increase in tocopherol content as a result of the specified constructs, then inventive step could be acknowledged, since none of the documents cited in the search report proposes suppressing maleylacetoacetate synthesis.

6. In the light of the data contained in the application, the **objective** technical problem addressed by the application is that of preparing transformed plants. Selecting from the variety of possible nucleic acids those that code for HPPD and HGD solves the problem in a non-inventive manner, since it is an arbitrary choice that does not result in a special technical effect. Consequently, an inventive step cannot be acknowledged on the basis of the objective technical problem.

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
WO00/08169	17 February 2000 (17.02.2000)	30 July 1999 (30.07.1999)	05 August 1998 (05.08.1998)
FR2 778 527	19 November 1999 (19.11.1999)	18 May 1998 (18.05.1998)	

2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>